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09/786,853	07/02/2001	Roy Oliver	PC16834.PM03	6616

7590

09/24/2003

Engene C Rzucidlo  
Greenberg Traurig  
885 Third Avenue  
New York, NY 10022

EXAMINER

BENNETT, RACHEL M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/24/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/786,853

Applicant(s)

OLIVER ET AL.

Examiner

Rachel M. Bennett

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 10-28 is/are pending in the application.
- 4a) Of the above claim(s) 23-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 11-22 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The examiner acknowledges receipt of Amendment C filed 6/26/03.

#### ***Election/Restrictions***

1. Newly submitted claims 23-28 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 23-26 are drawn to a method of preparing an implant and claims 27-28 are drawn to a system for injecting an implant composition.

Since applicant has received two actions on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 23-28 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Specification***

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 11-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Oliver et al. (US 5397353).

Oliver et al. disclose a collagenous tissue preparation suitable for homotransplantation or heterotransplantation. The preparation is a non-resorbable, non-antigenic collagenous material

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which retains the natural structure and original architecture of the natural tissue. The material is substantially free of non-fibrous tissue proteins, glycoproteins, cellular elements and lipids. The tissue preparation is recolonized by host cells and revascularized after implantation into the host. See abstract. Freshly cut dermis is extracted with acetone with one or more changes. The dermis is placed in buffer or saline solution to remove the acetone. See cols 4-5. In Example 1, Oliver discloses small pieces (0.2.times.0.2 cm.) pieces of split-thickness rat skin were explanted onto pieces of the new material measuring 1.times.1 cm, or when dispersed epidermal cells were placed onto the new material, complete coverage with layered epithelium occurred with 8-9 days by epidermal cell migration and proliferation from the explants. The new collagenous sheet material will be suitable for use in human and veterinary surgery for the treatment of hernias, skin wounds including burns, correction of facial deformities, tendon damage, in various arthroplasties and generally in plastic and reconstructive surgery. See cols. 5-6. Claims 1-2 disclose a non-resorbable, substantially non-antigenic collagenous fibrous tissue preparation of human or animal tissue origin, which is suitable for homo- or heterotransplantation as a permanent repair for cutaneous wounds and soft tissue injuries, which preparation retains the natural structure and original architecture of said human or animal tissue, is substantially free of non-fibrous tissue proteins and glycoproteins, is substantially free of cellular elements, is substantially free of lipids and lipid residues and is non-cytotoxic, wherein said preparation is capable when implanted of being recolonized by host cells and revascularized while being resistant to calcification and preparation as claimed in claim 1 additionally substantially free of antigenic polysaccharides and mucopolysaccharides. Claims 4 discloses an implant for the permanent repair of cutaneous or soft tissue injuries in humans

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which comprises a sheet of substantially non-antigenic collageneous fibrous tissue preparation of claim 1. Claim 6 discloses an implant as claimed in either of claims 4 in which the implant is formed from a sheet of fibrous collagenous tissue which has been cross-linked by means of a polyisocyanate. Therefore, these claims are anticipated.

***Allowable Subject Matter***

4. Claim 10 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

5. Applicant's arguments filed 6/26/03 have been fully considered but they are not persuasive.

6. Applicants argue Oliver does not specifically disclose an implant composition capable of use as part of an application comprising a paste, gel or injectable solution. In response to applicant's argument that Oliver does not specifically disclose an implant composition capable of use as part of an application comprising a paste, gel or injectable solution, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, the rejection is maintained.

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*Conclusion*

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600